

**BEFORE THE
MISSOURI BOARD OF PHARMACY
STATE OF MISSOURI**

IN RE:)
)
TEVA ANIMAL HEALTH, INC.) **Case #2010-004513**

**ORDER OF THE MISSOURI BOARD OF PHARMACY
ISSUING TEVA ANIMAL HEALTH, INC., A DRUG DISTRIBUTOR LICENSE
SUBJECT TO PROBATION**

Comes now the Missouri Board of Pharmacy ("Board") and issues its ORDER granting a PROBATED drug distributor license, license number 2010028799, to Teva Animal Health, Inc. ("TEVA") pursuant to the provisions of Section 324.038, RSMo. As set forth in Section 324.038, RSMo, TEVA may submit a written request for a hearing to the Administrative Hearing Commission seeking review of the Board's decision to issue a probated license to TEVA. Such written request must be submitted to the Administrative Hearing Commission within thirty (30) days of issuance of this Order. The written request should be addressed to the Administrative Hearing Commission, P.O. Box 1557, Truman Building Room 640, Jefferson City, MO 65102-1557. If no written request for review is received by the Administrative Hearing Commission within the thirty (30) day period, the right to seek review of the Board's decision shall be waived.

The disciplinary period shall become effective immediately upon issuance of TEVA's license as a drug distributor. Should TEVA file a written request for review of this Order, the terms and conditions of the Order shall remain in force and effect unless and/or until such time as the Administrative Hearing Commission issues an order contrary to this Order.

FINDINGS OF FACT

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo, for the purpose of executing and enforcing provisions of Chapter 338, RSMo.

2. TEVA filed an application for a drug distributor license with the Board on or about July 20, 2010. The Board issued it a temporary drug distributor license on or about August 17, 2010. The license issued pursuant to this Order replaces the temporary drug distributor license issued on August 17, 2010. This probated drug distributor license is for the facility owned by TEVA at 3915 South 48th Street Terrace, St. Joseph, Missouri, that was inspected by an inspector for the Board on August 17, 2010.

3. TEVA operated as a drug distributor since at least December 2005 without a valid license to do so.

4. During an inspection of its facilities by a Board of Pharmacy inspector on August 17, 2010, the inspector learned that TEVA had operated as a drug distributor in Missouri since at least 2005, by shipping legend drugs and items, including, but not limited to, holding raw materials labeled as legend drugs and then transferring those legend drugs to other drug distributors and to manufacturing facilities, without having a drug distributor license. TEVA is under an injunction from the Food and Drug Administration for distributing adulterated animal drugs due to non-conformance with current Good Manufacturing Practices, with the injunction applying to all of its facilities in St. Joseph, Missouri.

5. Based on information received by the Board, pursuant to Section 338.055, RSMo, the Board concluded TEVA engaged in conduct which would be grounds for denying TEVA a license, or if currently licensed by the Board, disciplinary action by the Board against its drug distributor license.

CONCLUSIONS OF LAW

6. TEVA's conduct as alleged above is cause for the Board to deny TEVA a license to be a drug distributor pursuant to Section 338.055.1 and .2, RSMo, which states in pertinent parts:

1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his or her right to file a complaint with the administrative hearing commission as provided by chapter 621, RSMo.

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

(8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, including, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state.

7. Section 324.038, RSMo, provides in pertinent part:

1. Whenever a board within the division of professional registration, including the division itself when so empowered, may refuse to issue a license for reasons which also serve as a basis for filing a complaint with the administrative hearing commission seeking disciplinary action against a holder of a license, the board, as an alternative to refusing to issue a license, may, at its discretion, issue to an applicant a license subject to probation.

8. The Board hereby issues this ORDER in lieu of denial of TEVA's request for a drug distributor license in Missouri pursuant to Section 324.038, RSMo.

9. Pursuant to the provisions of Section 324.038, RSMo, the Board hereby issues drug distributor license number 2010028799 to TEVA in lieu of denial of TEVA's request for a license to practice as a drug distributor in Missouri for its location at 3915 South 48th Street Terrace, St. Joseph, Missouri. License number 2010028799 is issued subject to the terms and conditions set forth herein below.

ORDER

Based on the foregoing and in lieu of denying TEVA ANIMAL HEALTH, INC., a drug distributor license, the Board issues TEVA a license subject to PROBATION for four (4) years (hereinafter "disciplinary period"). The terms of the disciplinary period shall be:

1. Respondent shall pay all required fees for licensing to the Board and shall renew its drug distributor license prior to October 31 of each licensing year.

2. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

3. If, after disciplinary sanctions have been imposed, the Respondent fails to keep its drug distributor license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

4. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after the date of this Order, stating truthfully whether or not it has complied with all terms and conditions of this disciplinary order.

5. Respondent shall make a representative of the drug distributor available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.

6. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Order.

7. The parties to this Order understand that the Board of Pharmacy will maintain this Order as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

8. Upon the expiration of the disciplinary period, TEVA'S license as a drug distributor shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that TEVA has violated any term or condition of this Order, the Board may, in its discretion, after an evidentiary

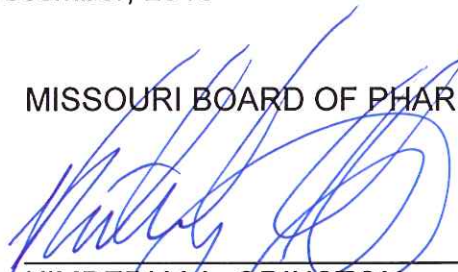
hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline TEVA'S drug distributor license.

9. No order shall be entered by the Board pursuant to the preceding paragraph of this Order without notice and an opportunity for a hearing before the Board in accordance with provisions of Chapter 536, RSMo.

10. If the Board determines that TEVA has violated a term or condition of this Order, which violation would be actionable in a proceeding before the Administrative Hearing Commission or the Circuit Court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Order in its determination of appropriate legal actions concerning that violation.

SO ORDERED this 7th day of December, 2010

MISSOURI BOARD OF PHARMACY



KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR